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10/613,018	07/07/2003	Ursula-Henrike Wienhues	2923-543	8627
6449 7590 10/10/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W.			EXAMINER	
			STEELE, AMBER D	
SUITE 800 WASHINGTON, DC 20005		ART UNIT	PAPER NUMBER	
,			1639	
			NOTIFICATION DATE	DELIVERY MODE
			10/10/2008	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

## Application No. Applicant(s) 10/613.018 WIENHUES ET AL. Office Action Summary Examiner Art Unit Amber D. Steele 1639 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status Responsive to communication(s) filed on 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.3.4.6-22 and 25 is/are pending in the application. 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected 7) Claim(s) is/are objected to. 8) Claim(s) 1, 3-4, 6-15, 19-22, and 25 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

3) Information Disclosure Statement(s) (PTO/S5/08)

Attachment(s)

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### DETAILED ACTION

#### Status of the Claims

 The amendment to the claims received on September 6, 2006 canceled claim 2 and amended claim 1

The amendment to the claims received on April 25, 2007 canceled claims 23-24 and amended claim 1

The amendment to the claims received on November 19, 2007 amended claims 1 and 16.

The amendment to the claims received on May 7, 2008 amended claim 1, canceled claim 5, and added new claim 25.

Claims 1, 3-4, 6-22, and 25 are currently pending.

Claims 1, 3-4, 6-15, 19-22, and 25 are currently under consideration.

## Previous Election/Restrictions

- 3. Applicants elected, without traverse, Group I (previous claims 1-15 and 19-22) in the reply filed on February 10, 2006. Claims 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.
- Due to the claim amendments, the previous species requirement is withdrawn. A new species requirement is provided below.

#### Election/Restrictions

 This application contains claims directed to the following patentably distinct species of the claimed invention for elected Group I. Election is required as follows. The applicant is required to elect a single, specific species from **each** of the following species A-B.

A. a species of first antigen (please refer to claims 4, 9-15, and 19-22)

Applicant must elect, for the purposes of search, a single, specific species of first antigen.

B. a species of second antigen (please refer to claims 3-4, 8-15, 19-22, and 25)

Applicant must elect, for the purposes of search, a **single**, **specific species** of second antigen.

For example, are the antigens of formula Ia or Ib; is the second antigen biotinylated; does the marker within the first antigen comprise a hapten; what are P, T, L, n, and/or m; is a spacer present; are the antigens multimeric and comprising multiple identical epitope regions; are the antigens recombinant; are the antigens fusion polypeptides comprising mosaic peptides; is a branching formula present?

- 6. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.
- 7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

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9.

8. There is an examination and search burden for these patentably distinct species due to

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their mutually exclusive characteristics. The species require a different field of search (e.g.,

searching different classes/subclasses or electronic resources, or employing different search

queries); and/or the prior art applicable to one species would not likely be applicable to another

species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101

and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of a species to be examined even though the requirement may be traversed (37

CFR 1.143) and (ii) identification of the claims encompassing the elected species, including

any claims subsequently added. An argument that a claim is allowable or that all claims are

generic is considered nonresponsive unless accompanied by an election.

10. The election of the species may be made with or without traverse. To preserve a right to

petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the election of species requirement, the election shall be treated as

an election without traverse. Traversal must be presented at the time of election in order to be

considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate

which of these claims are readable on the elected species.

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11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

- 12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.
- 13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **Future Communications**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/ Patent Examiner, Art Unit 1639

October 7, 2008